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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,507	02/10/2004	Harold A. Brokish	1440-005	1490

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/775,507	Applicant(s) BROKISH, HAROLD A.	
	Examiner Medina A Ibrahim	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-33 are pending and are under examination.

Objections

Claims 1, 7, 26-27, and 32 are objected to for failing to recite complete ATCC accession information. The ATCC Accession no must be filled in as appropriate.

Claim Rejections - 35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the recitation "KW4U110". Since the name "KW4U110" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name "KW4U110" does not clearly identify the claimed seeds, plants, and plant parts, and does not set forth the metes and bounds of the claimed invention. The name appears to have been arbitrarily assigned and can be changed. The specific characteristics associated therewith can also be modified. Amending claims 1, 17 and 19 to recite the ATCC deposit number in which seed of corn inbred line KW4U110 has been deposited would overcome the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. The specification does not disclose a reproducible method to obtain the exact same seed and it is unclear if the seed is readily available to the public.

The statement on page 32 of the specification indicating Applicant's intention to make an enabling deposit of the claimed invention with ATCC is noted. However, there is no indication that the seed has been deposited and no indication that the seed is available to the public. A deposit of at least 2500 seeds is required for enablement purpose.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or statement by an attorney of record over his or her signature and registration number, stating that the seed has been deposited under the Budapest Treaty and the seed will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. See 37 C.F.R. 1.808-1.809 for additional explanation of these requirements.

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If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 days or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see C.F.R. 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Written Description

Claims 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a hybrid seed produced by crossing a plant of the corn inbred line KW4U110 with a different corn plant. In contrast, Applicant describes inbred corn line KW4U110 having specific combination of genotypic and phenotypic characteristics that distinguish the line from other corn lines. Applicant also describes

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few F1 hybrid seed/plants of KW4U110 for performance comparison with known hybrids. However, it is unclear if the seed of said F1 hybrids of the inbred KW4U110 have been deposited and are publicly available. These are genus claims.

The Federal Circuit court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). The court also stated "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material". *Id.* Further, the court stated that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus". *Id.*

Applicant has not described the morphological and/or genotypic characteristics for all hybrid corn plants and seeds produced by crossing the inbred corn line KW4U110 with another unidentified corn plant. No specific morphological or genotypic characteristics that distinguish the claimed hybrid corn plants/seeds from other corn plants and seeds are described. Furthermore, variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one non-KW4U110 parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-KW4U110 inbred parent. As a result, the complete genomic structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ.

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The phenotypic characteristics of the hybrid depends on how each allelic product interacts with the corresponding allelic product inherited from the other genome, as well as how each gene product interacts with the other gene products in the genome. Given that a claimed hybrid corn plant comprises a set of alleles inherited from each parent and these two sets of alleles interact in a variety of ways to determine the hybrids morphological and physiological traits, one cannot correlate the alleles inherited from KW4U110 alone, with the phenotype of the hybrid progeny. Therefore, the deposit of KW4U110 seeds is insufficient to provide an adequate written description of all hybrid progeny that may be produced by crossing KW4U110 plants with second, distinct corn plants.

Tables 2 and 3 describe the performance comparison of few hybrids of KW4U110 with prior art hybrids. However, these hybrids are not representative species, given the large genus claimed and the variation expected among the hybrids. Given the vast number of hybrids encompassed by the claims; the substantial variation in phenotypes expected among these hybrids; and the vast number of unidentified non-KW4U110 involved in the breeding, the disclosure of a single hybrid of the inbred KW4U110 will not provide adequate written description for all F1 hybrids from inbred KW4U110.

Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See Written Description Requirement published in Federal Registry/Vol.66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

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Remarks

The claims are deemed free of the prior art, given that the prior art does not teach or fairly suggest inbred KW4U110 having all the characteristics as described in Table 1 ; nor that the prior art teaches a hybrid corn seed/plant produced from the inbred corn KW4U110.

Contact Information

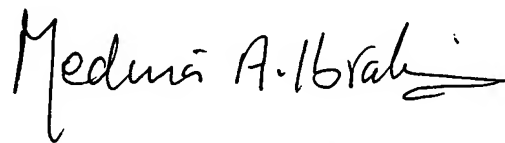
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/18/05

Mai



MEDINA A. IBRAHIM
PATENT EXAMINER